

REMARKS

This amendment is responsive to the Office Action of October 25, 2006. Reconsideration and allowance of claims 1-24 is requested.

Status of the Claims

Claims 1-18 and 22-29 are pending.

Claims 2-4, 14, and 19-21 stand withdrawn from consideration.

Claims 1, 10, 11, and 23 are amended.

Claims 25-29 are added.

Claims 19-21 are cancelled.

The Office Action

The restriction requirement was maintained.

The specification was objected to for informalities.

Claims 23 and 24 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Claims 1, 9, 18, and 22-24 stand rejected under 35 U.S.C. §102(b) as being unpatentable over Ernst and Race (Comparative Analysis of Scrapie Agent Inactivation Methods, *J. Virol. Methods*, 41: 193-202 (1993)).

Claims 1 and 5-9 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ernst and Race (1993) in view of Werner, et al. (Estimation and Verification of the Environmental Fate of *O*-benzyl-*p*-chlorophenol, *Arch. Environ. Contam. Toxicol.*, 12:569-575 (1983)).

Claims 10-13 and 15-17 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Ernst and Race (1993) in view of Werner, et al. (1983), and further in view of Cooper (A Comparative Study of the Effects of Various Factors Upon the Germicidal and Protein Precipitating Powers of the Phenols, *Biochem. J.*, 7(2) 175-185 (1913)) and Yamamoto, et al. (Glycidol Degrades Scrapie Mouse Prion Protein, *J. Vet. Med. Sci.*, 63(9): 983-990 (2001)).

Objections

The specification has been amended to remove reference to FIGURE 6. Accordingly, it is requested that the objections to the specification be withdrawn.

§112 rejections

Claim 23 has been amended to replace xylanol with xylenol, as supported by the specification in TABLE 2. Accordingly, it is respectfully requested that the 35 U.S.C. §112, second paragraph, rejections be withdrawn.

The Present Application

Prions are resistant to many conventional treatment processes used for destruction of microorganisms. The conventional treatment for prion contaminated surfaces has been soaking in concentrated sodium hydroxide and/or exposure to high temperatures. Many instruments used for invasive surgery are unsuited to such aggressive treatments and thus are generally discarded if they are known or suspected of being contaminated with prions. The present inventors have found that by treating prion contaminated surfaces with a phenol-based composition, prions can be destroyed without the need for aggressive treatments.

The References of Record

Ernst and Race discloses treating a scrapie-infected hamster brain homogenate with LpH. As mentioned in the Ernst and Race article, LpH is an aqueous acid phenolic disinfectant which contains o-benzyl-p-chlorophenol at 6.1%, as well as p-tertiary amylphenol at 3%, and phenylphenol at 0.5%.

Werner discloses the use of o-benzyl-p-chlorophenol (OBPC) as a disinfectant in hospitals.

The Cooper reference notes that the addition of sodium chloride increased the bacterial action of phenol and its solubility in proteins. The effects are noted at 10% salt and higher at 20% salt. The proteins cited in the Cooper work were gelatin and dialyzed egg-albumin.

The Yamamoto reference discloses the effects of glycidol (GLD), a liquid epoxide, on scrapie-mouse protein. FIGURE 4 of Yamamoto shows the effect of salt concentration and pH on the effect of GLD.

**The Claims Distinguish Patentably
Over the References of Record**

Claim 1 has been amended to incorporate the subject matter of original claim 10. Claim 1 now calls for a method of treating a body which is contaminated

with prions. The method includes contacting the body with a composition comprising a phenol and a soluble inorganic salt to inactivate prions on the body.

The references of record do not suggest such a method. Ernst & Race (1993) discloses treating a scrapie-infected hamster brain homogenate with LpH. There is no suggestion in this reference that the composition include a soluble inorganic salt.

Werner (1983) discloses the use of o-benzyl-p-chlorophenol (OBPC) as a disinfectant in hospitals. However, there is no suggestion that the phenol be useful in the treatment of prions or that the phenol be combined with a soluble inorganic salt.

Cooper discloses the precipitation of proteins with phenols. There is no suggestion in Cooper that phenols would be effective at destroying prions. Rather, Cooper discloses an increase in germicidal power on bacterial proteins in the presence of very high salt concentrations.

Yamamoto discloses the treatment of prion protein with three epoxides, one being GLD. There is no suggestion in Yamamoto that these could be replaced with phenols.

Phenols are very different from epoxides in their composition and reactions. Yamamoto admits that the mode of action of GLD on prions is unknown, although there is some suggestion that GLD covalently binds to proteins. In contrast, Cooper discusses a de-emulsifying action of phenols on bacterial proteins. Thus, there is no basis for inferring that salt would have any benefit on the effectiveness of phenols, based on Yamamoto, particularly in view of the lack of any suggestion of any similarity in the modes of action of these chemicals.

Further, because prions have been shown to be remarkably resistant to most known chemical treatments, and have been shown not to behave like bacteria in many instances, it would not have been obvious to one of ordinary skill in the art that addition of an inorganic salt would improve the effectiveness of a phenol composition on the destruction of prions, based on tests on bacteria.

Accordingly, it is submitted that claim 1, and claims 2-9, 11-18, 22, and 25-28 dependent therefrom, distinguish over the references of record.

Claim 23 calls for a method of treating a body which is contaminated with prions. The method includes providing a composition comprising at least one phenol of the group identified at a concentration of at least 0.005M and an inorganic salt which is present at a concentration of at least 2% by weight. The body is

contacted with the composition to effect a log reduction of at least 4.1 for prions on the body.

The Ernst and Race reference makes no suggestion of treating a prion-contaminated body with a composition comprising a phenol and an inorganic salt. Accordingly, it is submitted that claim 23 distinguishes patentably and unobviously over the reference of record.

New claim 29 calls for a method of treating a body which is contaminated with prions. The method includes contacting the body with a composition to inactivate prions on the body, the composition comprising a phenol, a cosolvent, and a surfactant selected from the group consisting of sulphonic acids, sulfonates, and combinations thereof. Support for new claim 29 is to be found in the specification at page 9, line 4 and line 27-page 10, line 16 and in the example composition on page 11.

As illustrated in Example 1, TABLE 1, and Example 2, TABLE 1, a composition which includes a cosolvent (hexylene glycol) and a surfactant as claimed is particularly effective in the reduction of IFDO (a prion model) and, in some cases, has been found to be more effective than LpH.

The references of record do not suggest such a composition. Accordingly, it is submitted that claim 29 distinguishes over the references of record.

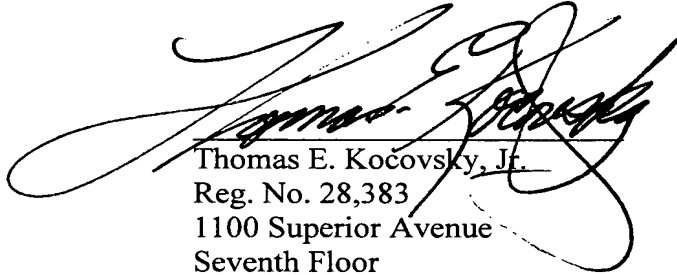
CONCLUSION

For the reasons set forth above, it is submitted that claims 1-18 and 22-29 distinguish patentably over the references of record and meet all statutory requirements. An early allowance of all pending claims is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, she is requested to telephone the undersigned at (216) 861-5582.

Respectfully submitted,

FAY SHARPE LLP

A large, stylized handwritten signature in black ink, which appears to read "Thomas E. Kocovsky, Jr.", is written over the printed name and address.

Thomas E. Kocovsky, Jr.
Reg. No. 28,383
1100 Superior Avenue
Seventh Floor
Cleveland, OH 44114-2579
(216) 861-5582